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(54) **NON-CORROSIVE STERILANT COMPOSITION**

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(51) **Int. Cl.**

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A01N 59/26	(2006.01)
A01N 37/16	(2006.01)
A61L 2/18	(2006.01)

(52) **U.S. Cl.** **424/616**; 424/601; 424/606; 424/613; 424/126; 514/557; 514/558; 514/560; 514/574; 514/714; 422/28; 422/29

(58) **Field of Classification Search** 424/601, 424/606, 613, 616, 126; 514/557, 558, 560, 514/574, 714; 422/28, 29
See application file for complete search history.

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(57) **ABSTRACT**

A non-corrosive, liquid, aqueous sterilant composition (as a concentrate or ready-to-use solution), which may be provided in two parts which are mixed prior to application, may comprise a peracid (in an equilibrium solution with an underlying carboxylic acid or mixtures of alkyl carboxylic acids and peroxide), inorganic buffering agent, and water. It has been found that the use of this simplified system, even in the absence of additional components which have been thought to be desirable for sterilants used on metal parts (e.g., copper and brass corrosion inhibitors, chelating agents, anti-corrosive agents) display excellent performance and that these additional components are not necessary, and that the presence of these additional materials at least complicates disposal of the spent solutions and could complicate compatibility of the sterilant solutions with some polymeric materials, especially where organic materials are used as the additional components, which organic materials may interact with, dissolve or solubilize in the polymeric materials.

6 Claims, 3 Drawing Sheets

FIG. 1

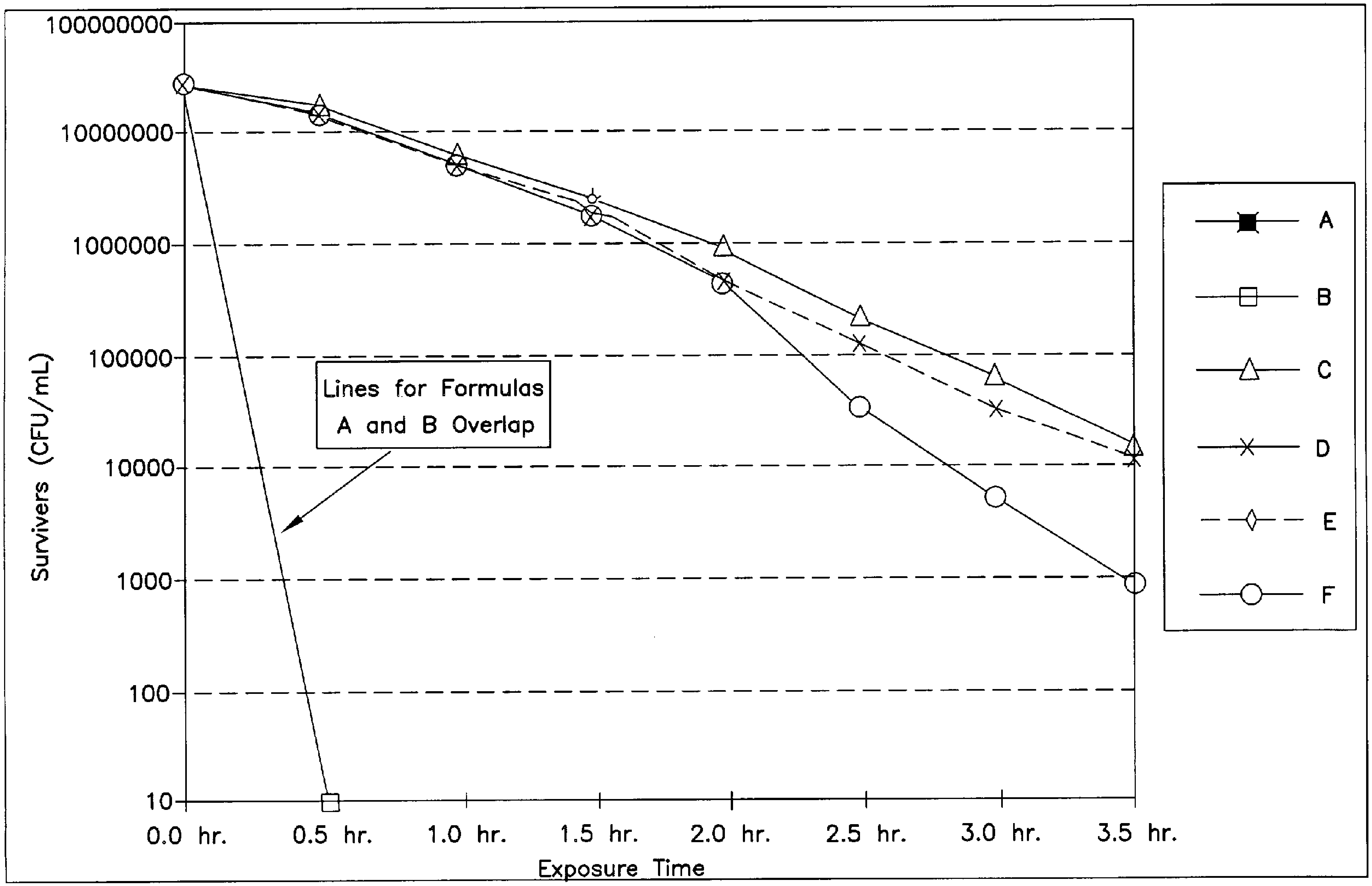

Survivers (CFU/mL)
100000000
10000000
1000000
100000
10000
1000
100
10
0.0 hr.
0.5 hr.
1.0 hr.
1.5 hr.
2.0 hr.
2.5 hr.
3.0 hr.
3.5 hr.
Exposure Time
Lines for Formulas A and B Overlap
A
B
C
D
E
F

FIG. 2

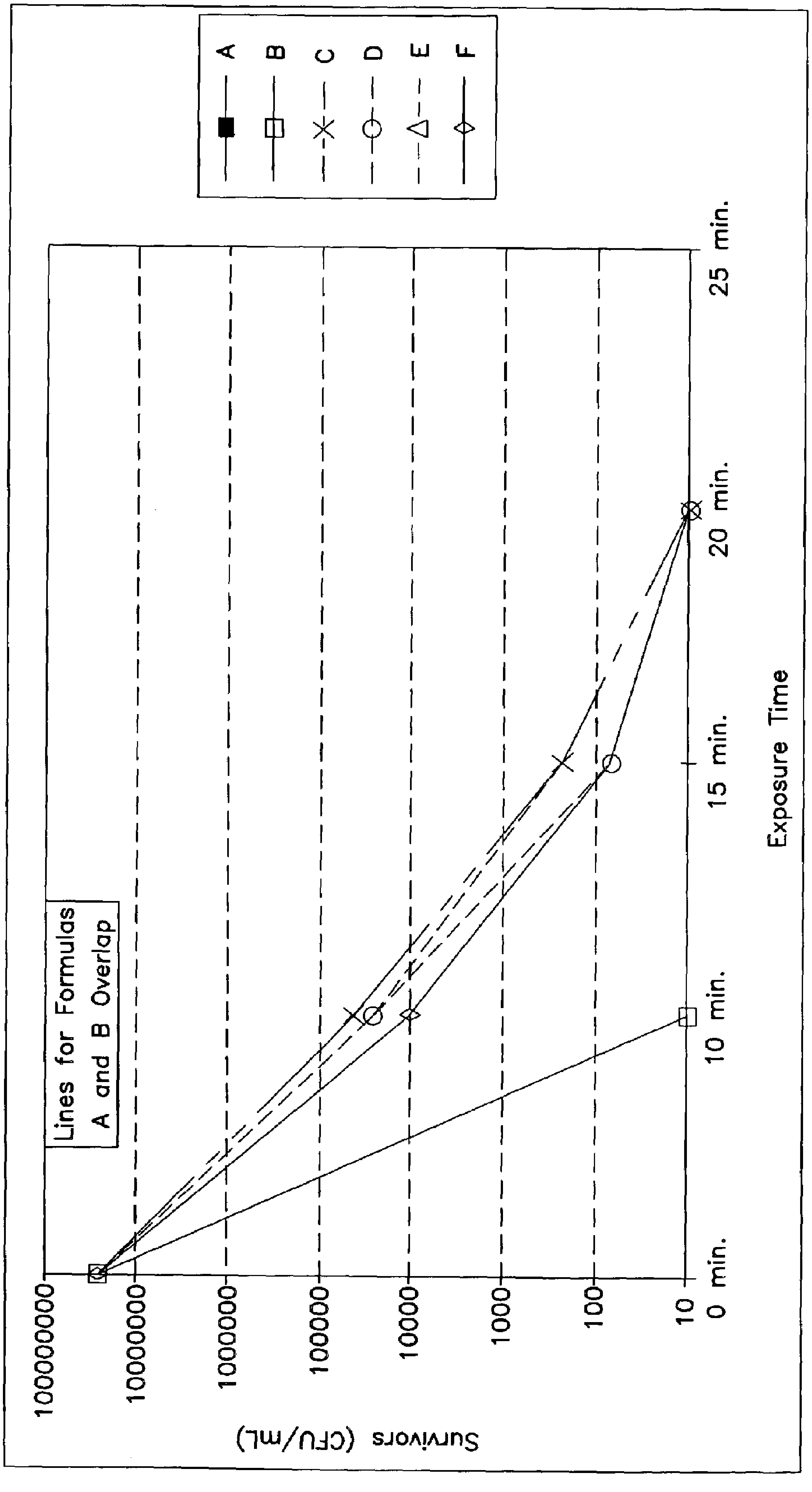
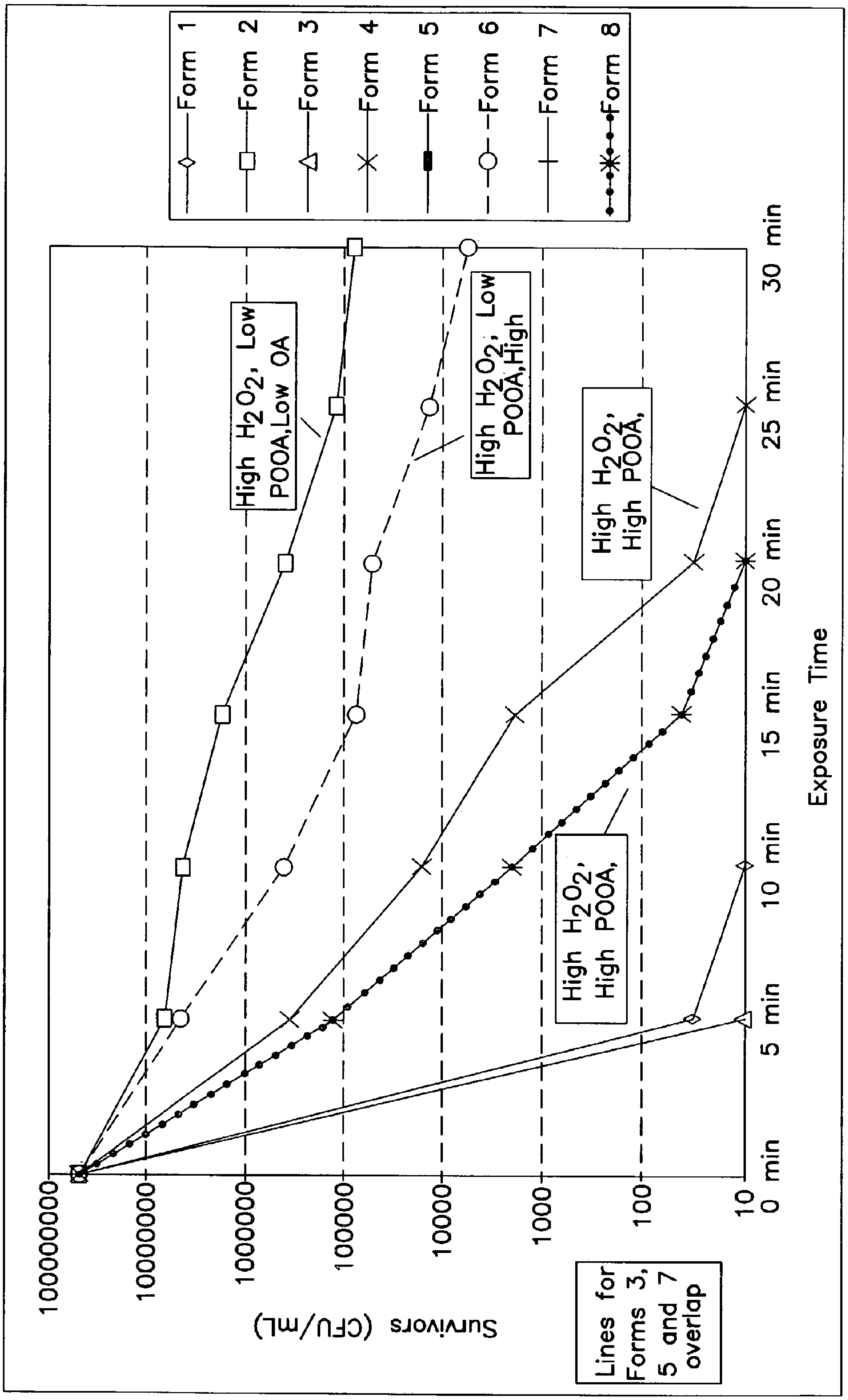

Survivors (CFU/mL)
100000000
10000000
1000000
100000
10000
1000
100
10
0 min.
10 min.
15 min.
20 min.
25 min.
Exposure Time
Lines for Formulas
A and B Overlap
A
B
C
D
E
F

FIG. 3


Form 1
Form 2
Form 3
Form 4
Form 5
Form 6
Form 7
Form 8
Survivors (CFU/mL)
100000000
10000000
1000000
100000
10000
1000
100
10
0 min
5 min
10 min
15 min
20 min
25 min
30 min
Exposure Time
High H_2O_2, Low POOA, Low OA
High H_2O_2; Low POOA, High
High H_2O_2, High POOA,
High H_2O_2, High POOA,
Lines for Forms 3, 5 and 7 overlap

NON-CORROSIVE STERILANT COMPOSITION

This application is a Continuation of application Ser. No. 09/447,328, filed Nov. 22, 1999, now U.S. Pat. No. 6,589,565, which claims priority to U.S. Provisional Application Ser. No. 60/109,565, filed Nov. 23, 1998, which applications are incorporated herein by reference.

The present invention relates to compositions which can be used to safely and effectively disinfect surfaces and articles against microbiological forms. The compositions are easily handled, tend to be non-corrosive to the types of polymeric, elastomeric and metal surfaces found in medical instruments, are relatively shelf-stable, and may be prepared quickly and easily by simply blending component solutions.

The importance of the sterilization of medical instruments and implants has been understood for more than two centuries. The need for sterilization has become even more important recently with the appearance of strains of microbiological forms which are resistant to conventional microbiocides such as antibiotics. It has become very important to sterilize medical devices to kill or remove the more resistant strains of microbiological forms before they infect a patient. Additionally, the sterilants must be generally effective against microorganisms covering a wide range of classes and species, with U.S. Government standards requiring efficacy against both bacteria and spores.

Sterilization of medical devices has been performed for many years by immersing the medical devices in an atmosphere which is antagonistic to the survival of the microbiological forms. Among the environments which have been used to attempt to sterilize medical instruments include, but is not limited to, steam, alcohols, ethylene oxide, formaldehyde, gluteraldehyde, hydrogen peroxide, and peracids. Each of these materials has its benefits and limitations. Ethylene oxide tends to be very effective against a wide range of microorganisms, but it is highly flammable and is generally used in a gas phase which may require more stringent environmental restraints than would a liquid. Alcohols are similarly flammable and must be used in very high concentrations. Steam has a more limited utility, having to be used in a controlled and enclosed environment, requiring the use of large amounts of energy to vaporize the water, and requiring prolonged exposure periods to assure extended high temperature contact of the steam with the organisms. Hydrogen peroxide has limited applicability because it is unstable and not as strong as some other sterilants. The peracids have become more favorably looked upon, but they tend to be corrosive (being an oxidizing acid) and are not shelf stable.

U.S. Pat. No. 5,508,046 describes a stable, anticorrosive peracetic acid/peroxide sterilant comprising a concentrate including peracetic acid, acetic acid, hydrogen peroxide (in a ratio of 1:1 to 11:1 total acid/hydroxide), and 0.001 to 200 parts per million of stabilizers such as phosphonic acids and sodium pyrophosphates. The concentrates are diluted about 20 to 40 times so that the maximum concentration of stabilizer in the use solution would be about 10 parts per million. The stabilizers are described as acting as chelating agents by removing trace metals which accelerate the decomposition of the peroxides.

U.S. Pat. No. 5,616,616 describes a room temperature sterilant particularly useful with hard tap water comprising an ester of formic acid, an oxidizer (such as hydrogen peroxide or urea hydrogen peroxide), performic acid and water. The use of corrosion inhibitors (such as benzotriazoles, azimidobenzene, and benzene amide) and stabilizers (unnamed) is also generally suggested.

U.S. Pat. No. 5,077,008 describes a method of removing microbial contamination and a solution for use with that method. The solution comprises a combination of five ingredients in water: 1) a strong oxidant (including, for example, organic peroxides, peracids, an chloride releasing compounds, with peracetic acid in a concentration of 0.005 to 1.0% being preferred), 2) a copper and brass corrosion inhibitor (e.g., triazoles, azoles and benzoates), 3) a buffering agent (including, for example, phosphate), 4) at least one anti-corrosive agent which inhibits corrosion in at least aluminum, carbon steel and stainless steel selected from the group consisting of chromates and dichromates, borates, phosphates, molybdates, vanadates and tungstates, and 5) a wetting agent. A sequestering agent may be used to prevent the phosphates from causing precipitation in hard water.

U.S. Pat. Nos. 4,892,706 and 4,731,22 describe automated liquid sterilization systems having a plurality of modules which store the sterilant solution and the rinse solution. U.S. Pat. No. 5,037,623 describes a sterilant concentrate injection system which is a spill resistant, vented ampule system for use with sterilization systems.

Medical devices now include many polymeric components for reasons of material costs and ease of manufacture. Many of the systems and solutions designed for the sterilization of metal medical devices are not necessarily suitable for use with polymeric components, and may cause corrosion of the polymeric materials. It is therefore necessary to formulate sterilization compositions which are compatible with both metal and polymeric components of the medical devices. It is also always desirable to provide sterilization systems with fewer components in the composition, where the sterilization solutions do not significantly sacrifice microbiocidal activity and do not corrode the materials used in medical devices.

SUMMARY OF THE INVENTION

A non-corrosive, liquid, aqueous sterilant composition (as a concentrate or ready-to-use solution), which may be provided in two parts which are mixed prior to application, may comprise a peracid (in an equilibrium solution with an underlying carboxylic acid or mixtures of alkyl carboxylic acids and peroxide), inorganic buffering agent, and water. It has been found that the use of this simplified system provides excellent sterilization ability, even in the absence of additional components which have been thought to be desirable for sterilants used on metal parts (e.g., copper and brass corrosion inhibitors, chelating agents, anti-corrosive agents) which have been found to not be necessary. The presence of these additional materials at least complicates disposal of the spent solutions and could complicate compatibility of the sterilant solutions with some polymeric materials, especially where organic materials are used as the additional components, which organic materials may interact with, dissolve or solubilize in the polymeric materials.

The concentration of the components has shown itself to be important in providing non-corrosive effects towards a wide variety of structural materials in medical devices and yet providing effective sterilization effects against spores and bacteria, including tuberculosis bacteria in an acceptable amount of time.

An aqueous sterilant use solution according to the present invention may comprise a solution having a pH of from 5.0 to 7.0 comprising from 100 to 10,000 parts per million of a peroxy acid and 30 to 5000 parts per million of buffering agent, preferably without any organic anticorrosive agents. The aqueous sterilant solution may, for example, comprise from 100 to 10,000 parts per million of a peroxy acid, 30 to 5000 parts per million of buffering agent and a catalytically effective amount of a catalyst for peroxygenation of a carboxylic acid by hydrogen peroxide.

The aqueous sterilant solution may consist essentially of a solution having a pH of from 5.0 to 7.0 comprising from 100 to 10,000 parts per million of a peroxy acid, 30 to 5000 parts per million of buffering agent and a catalytically effective amount of a catalyst for peroxygenation of a carboxylic acid by hydrogen peroxide.

The method may particularly comprise mixing a first and a second solution to form a sterilizing solution comprising a peroxy acid, said first solution comprising a carboxylic acid, hydrogen peroxide and water, and said second solution comprising a buffering agent for pH between about 5 and 7, said sterilizing solution comprising at least 100 parts per million of peroxy acid at a pH of 5 to 7, immersing said article in said sterilizing solution for at least 5 minutes to sterilize said article, said first solution and second solution being free of organic anti-corrosion agents for brass and/or copper, and said article comprising a medical article having parts made of at least two materials selected from the group consisting of metals, polymers and rubbers.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a graph showing the reduction of *B. cereus* spores at 40° C.

FIG. **2** is a graph showing the reduction of *B. cereus* spores at 60° C.

FIG. **3** is a graph showing the reduction of *B. cereus* spores at 40° C.

DETAILED DESCRIPTION OF THE INVENTION

The aqueous sterilant compositions of the present invention comprise a peracid, water-soluble peroxide source, and carboxylic acid in a buffered solution at pH levels between about 5.0 and 7.0. The use of an inorganic buffering agent also enables the use of slightly water-soluble, higher molecular weight carboxylic acids in the formation of peroxy acids with the peroxide source thereby reducing the amount of deposits from fatty acid residue in the solution. Phosphate buffers are effective dispersants and suspending agents for these fatty acid residues.

The peroxy acid useful in the practice of the present invention may comprise any organic peroxy acid. These acids are well known in the art to be formed from any carboxylic acid containing compound. Normally they are prepared from carboxylic acids of the formula:

$$CH_3—(CH_2)n\text{-}COOH$$

wherein n is 0 to 18, preferably 0 to 12 and more preferably 0 to 10, with the corresponding peroxy acid having the formula:

$$CH_3—(CH_2)n\text{-}CO_3H$$

wherein n is as defined above. The alkyl moiety on the acid, $CH_3—(CH_2)n$- may be replaced with hydrogen or any, preferably low molecular weight, organic group so that the acid and the resulting peroxy acid may be represented by: $R—CO_2H$ and $R—CO_3H$, respectively. The molecular weight of R could be 1, but preferably should be between 15 and 155.

Carboxylic acids which are generally useful in the invention are those which comprise percarboxylic acids. Percarboxylic acids generally have the formula $R(Co_3H_n)$, where R is an alkyl, arylaklyl, cycloalkyl, aromatic or heterocyclic group, and N is 1, 2, or 3 and named by prefixing the parent acid with peroxy.

The peracid normally exists in an equilibrium state with the original or fundamental acid and the peroxide source, usually hydrogen peroxide. Typical peracids include peracids of C_1 to C_{12} carboxylic acids such as formic acid, acetic acid, propanoic acid, butanoic acid, pentanoic acid, hexanoic acid, heptanoic acid, octanoic acid, nonanoic acid, decanoic acid, undecanoic acid, dodecanoic acid, and the like. The term carboxylic acids as used in the practice of the present invention, unless otherwise limited, also includes mono- and di-hydroxycarboxylic acids such as glycolic acid, lactic acid and citric acid. An example of di-hydroxycarboxylic acid or di-hydroxy is tartaric acid, and also fumaric acid, which is an unsaturated di-hydroxycarboxylic acid. Diacids such as alpha-omega-dicarboxylicpropanoic acid, succinic acid, glutaric acid, adipic acid, and the like may also be used to form di-peracids. Peroxycarboxylic acids may also be present and included within the solutions of the present invention. Mixtures and combinations of the peracids may also be used in the systems of the invention, as well as other addenda as generally described herein.

The peroxide source is preferably an aqueous solution of hydrogen peroxide, but may also include such alternative peroxide sources as solutions of sodium peroxide, calcium peroxide, alkali salts of percarbonate and persulfate, and even organic peroxides such as dicumyl peroxide, dialkyl peroxides, urea peroxide, and the like, forming the basis of the solution of the hydrogen peroxide. The inorganic peroxides are preferred as the source of the solution of the hydrogen peroxide. The ratio of the peroxy acid to the hydrogen peroxide can also significantly influence the efficacy of the solutions of the invention, with higher ratios of the peroxy acid to the hydrogen peroxide preferred. For example, its is more desirable to have a ratio of at least 2:1 or 3:1 (peroxy acid to hydrogen peroxide), and more desirable to have higher ratios of at least 4:1, at least 5:1 or at least 8:1 or more (peroxy acid to hydrogen peroxide).

The buffering agent is a compound, again preferably an inorganic compound which will maintain a buffered pH level in the solution of the composition between 5.0 and 7.0. Buffering agents include, but are not limited to phosphates, borates, lactates, acetates, citrates, vanadates, tungstates, and combinations thereof, particularly alkali metal or alkaline metal salts of these agents. The use of phosphates exclusively or at least primarily (e.g., at least 50%, at least 65%, at least 75%, or at least 90 or 95% by weight of the buffering agents) is particularly useful. Trisodium phosphate has been found to be particularly desirable because of its ability to maintain the acid residues of the peroxy acids in solution where they will not form film in the solution which can be picked up by any sterilization apparatus or medical device which is being sterilized. It is interesting to note that phosphates have been generally taught to be avoided in sterilization solutions where hard water may be contacted because of the potential for calcium precipitation, yet in the present invention, the presence of phosphates reduces the formation of organic residue film on the surface of the solution. The buffering agent alone, even when a phosphate or especially when a phosphate and particularly trisodium phosphate, has been found to reduce corrosion by the solution on all surfaces. The use of phosphate(s) alone, in the absence of copper and brass corrosion inhibitors has been found to be an effective sterilant, and provide non-corrosive activity against a wide range of structural materials, including, but not limited to rubbers, plastics and metals, such as stainless steel, aluminum, polypropylene, teflon, acrylonitriletstyrenetbutadiene, polyolefins, vinyl resins (e.g., polyvinyl chloride, polyvinylbutyral), silicone resins and rubbers, and polyurethanes, and provide second tier protection for brass and copper. Although the peracids work more efficiently in their microbiocidal activity at highly acidic pH levels (below 4.0), those acidic levels are much more corrosive. The use of a buffering system which maintains the pH above 5.0 and preferably between about 5.0 and 7.0 still provides a microbiocidal activity at levels which meet all international standards, using anywhere from 150 to 10,000 parts per million peracid.

The sterilant can be used as a manual system or be used in an automated system. The sterilant can be provided as a one-part or preferably two part concentrate, with the peracid in one solution and the buffer in the second solution. For example, in a two-part system, a peracid concentrate may be formed having 0.01% to 1% by weight peracid (e.g., peracetic acid), 0.003% to 1% by weight ppm hydrogen peroxide, 0.01% to 1% by weight acid (e.g., acetic acid), and the buffer solution may comprise, for example, from 0.5 to 75,000 ppm buffering agent (e.g., anhydrous trisodium phosphate) in water. Mixtures of these types of addenda, including the buffering agents and peracids, are clearly useful in the practice of the present invention. It is preferred that the concentrates have active ingredient contents at the higher levels of these ranges such as 0.1% to 15% by weight peracid, 5% to 80% by weight peroxide, 5% to 80% by weight acid and 0.1% to 15% by weight buffering agents. The diluted to use solution would preferably contain sufficient actives to provide 0.01% to 1.0% by weight peracid at a pH between about 5.0 and 7.0. The use solution need not contain any effective amount of many of the additives which prior art systems have required for non-corrosive effects (such as the organic anti-corrosive agents such as the triazines, benzotriazoles, azoles and benzoates), and yet provide a wider disclosed range of non-corrosivity against the many available surfaces of medical devices. The use solutions of the present invention may comprise a simplest solution comprising peracid (along with the acid and peroxide in equilibrium), buffering agent in an amount to provide a pH of from about 5.0 to 7.0, and water (preferably deionized water). This solution may be modified by the addition of individual agents such as chelating agents, surfactants (also referred to in the literature for sterilant compositions as wetting agents), and anti-corrosion agents. A typical concentrate solution which may be diluted to a use solution might comprise, 0.1% to 15% by weight peracid, 0.1% to 15% by weight buffering agent[, with the remainder as water and other addenda as generally described herein (e.g., from 99.6 to 78% by weight water). These and other aspects of the invention will be further described by reference to the following, non-limiting examples.

These data show that a preferred range for the concentration of peroxide in the solution (particularly as evidenced by hydrogen peroxide) less than 150 ppm, preferably less than 100 up to 80,000 ppm, still more preferably less than 100, less than 75 and less than 50 ppm. In the examples, POAA represents peroxyacetic acid, AA represents acetic acid, POOA represents peroxyoctanoic acid, and Oct. Acid represents octanoic acid. Dequest™ are commercially available materials which may be used in the solutions of the present invention. Dequest™ 2000 comprises aminotri(methylene-phosphonic acid), Dequest™ 2010 comprises 1-hydroxyethylidene-1,1-diphosphonic acid, and Dequest™ 2006 comprises aminotri(methylene-phosphonic acid) pentasodium salt. Dequest acts as a chelator for heavy metals. The data also shows that sporicidal activity of compositions with higher molecular weight peracids increase with higher proportions of the peracid as compared to the acid.

The presence of a catalyst for the formation of the peracid in the sterilization compositions of the present invention also is a novel aspect of the present invention which could act to maintain the level of peracid in the solution during use.

CORROSION EXAMPLE I

Experimental

In the following comparison example, a formulation according to the present invention comprising 2.69 weight percent of a 13% solution of peracetic acid made by combining 78% glacial acetic acid, 21% hydrogen peroxide (35% by weight in water), and 1% hydroxyethylenediamine phosphonate was compared to a commercial sterilization formulation (CSF) comprising a mixture of sodium perborate and tetraacetyl ethylenediamine with a buffer to provide a use solution of pH 8, with its necessary sterilization activator. The CSF composition (referred to as Powder PAA) comprises a powder source of peracetic acid (with a solid peroxide source) without a buffering agent, and was compared to a liquid solution of peracetic acid (PAA) made according to the present invention (referred to as Liquid PAA) by admixture of acetic acid and hydrogen peroxide solution with 1% by weight of hydroxyethylenediamine phosphonate catalyst to form the solution of peracetic acid (with the equilibrium amounts of acetic acid and hydrogen peroxide) at a pH of 6.0 provided by 3.0% by weight trisodium phosphate. This commercial CSF product requires mixing of a dry powder, with a delay required for the activator TAED (tetra acetyl ethylene diamine) by reaction with sodium perborate to generate peracetic acid and microbiocidal activity in the components.

Test Parameters:

The test was performed on pieces of an Olympus flexible endoscopes using a washer/disinfector to reduce manual variables. The test parameters were room temperature conditions, with the following immersion times:

Sample	Cycles	Immersion Time
Liquid PAA	1	10 minutes
Powder PAA	1	15 minutes
Sample	Application Time	
Liquid PAA	24 hours	
Powder PAA	8 hours	

The test was performed by completely immersing separate test pieces S1 to S7 and W1 to W28 in each of the solutions.

Test Pieces	
Item	Parts
S1–S7	Parts of endoscope
S8 and S9	Insertion tube
S10	Light guide tube
W1–W28	Parats of washer/disinfector

-continued

Sample No.	Material (base)	Surface Control	Place of the Parts
S1	A5056BD-H32 Resin	black painting	connector to LS
S2	Polysulfone	black painting	main body
S3	SUS304 Resin	El. black coating	outside (hidden)
S4	Silicone Rubber	—	outside
S5	Polybutadiene PB-60	—	outside
S6	Mod. PPO Polyphenyleneoxide	black painting	main body
S7	A5056BD-H32 Resin	black alumite	eyepiece
S	Polyurethane	primary coat Z	insertion tube
S	Polyurethane	primary coat V	insertion tube
S	Polyurethane		light guide cable
W1	Stainless Steel		inner pipe system
W2	Stainless Steel		inner pipe system
W3	epoxy resin + coating		heating panel
W4	Polyethylene		basin
W5	Polypropylene		basin
W6	Polyacetate		connector
W7	Polysulfone		part of top cover
W8	Silicone Rubber		sealing
W9	Polyvinyl chloride		inner pipe system
W10	Polyvinyl chloride (hard)		inner pipe system
W11	Acrylic polymer		parts in the basin
W12	Ethylene/propylene		inner pipe system
W13	Ethylene/propylene rubber		inner pipe system
W14	Acrylate modified PolyVinylChloride		top cover
W15	Butyl-nitrile rubber + Phenol		parts in the basin
W16	Teflon		name plate in basin
W17	Butyl-nitrile rubber		sealing
W18	Polyurethane		?
W19	Acrylonitrile/butadiene/styrene		top cover
W20	modified PPO		top cover
W21	Butyl rubber		sealing
W22	fluorinated rubber		sealing
W23	alumina ceramic		parts of pump system
W24	Teflon		parts of pump system
W24	Teflon rubber		parts of pump system

CONCLUSION

The samples were carefully inspected to evaluate the cosmetic effects (corrosion effects) on the various pieces. The first examination (Item 1) was for parts of the endoscope. The second examination (Item 2) was for the insertion tube. The third examination (Item 3) was for the light guide tube. The fourth examination (Item 4) was for the washer/disinfector. The samples performed substantially identically, with both solutions showing only a slight cosmetic change in painted black surface of the endoscope (S3 surface). No functional or cosmetic changes were noted on any other sample. The simplicity of use for the Liquid PAA system was very noteworthy, with no delay in mixing or reaction time. The solutions could be directly added into an automated system while the CSF Powder PAA system would have required premixing and activation time before it could have been used in an automatic system.

CORROSION EXAMPLE II

Experimental

A corrosion study was performed to evaluate peracid containing formulas with and without buffer addition upon selected metals, plastics and rubbers.

Testing was conducted with two peracid formuations of 500 ppm (parts per million) peracetic acid (A) and 5000 ppm peracetic acid (B) concentration without buffer; and, two identical formulas (C and D respectively) with exception of buffer addition admixture.

Coupons were completely immersed in 200 mls of defined test solution contained in covered 8 ounce glass jars maintained at 50° C. within an environmental chamber. Solutions were changed daily. Study was conducted over a 14 day time period. For each test material, a control was also run which is a coupon of stated material placed within a covered 8 ounce glass jar having no test solution.

Coupons were pretreated before the corrosion study began, and postreated before final comparitive measurements and visual observations were performed. Metal coupons were precleaned according to ASTM Vol. 3.02, G31–72 and 3.02, G1–90 protocol and post-treated accordingly prior to final measurement. Test conditions were modified from the ASTM protocol as explained in above paragraph. Plastic and rubber coupons were only rinsed with deionized water and air dried prior to corrosion study; and, similarly treated prior to final measurement and visual observation.

CONCLUSION

Addition of buffer admixture to peracetic acid composition test solutions significantly improves metals protection. The effect is less noticeable on test plastics; but, protection is provided selected test rubbers.

PART IA: FORMULA - PERACID COMPONENT
HIGH POAA - LOW H202 PERACID FORMULA KX-6091

ITEM	RAW MATERIAL	WT. %	GM/ 10000
10	Acetic Acid	78.00	7800.00
20	Hydrogen Peroxide 35%	21.00	2100.00
30	Dequest ™ 2010 (60%)	1.00	100.00
	Total	100.00	10000.00

Mixing Instructions:
Batch was prepared by direct weighing on Mettler PM 16 Top Loading Balance into a 5 gal HMW/HDPE (high molecular weight/high density polypropylene) pail. The batch was mixed for 65 minutes using a lab mixer equipped with a plastic coated stir rod and blade.

PART IB: FORMULA - ADMIXTURE OF IA AND BUFFER COMPONENT FORMULAS A, B, C, D CORROSION STUDY USE DILUTIONS

		(A)		(B)		(C)		(D)	
ITEM	Material	WT. %	GM/ 4500	WT. %	GM/ 4500	WT. %	GM/ 4500	WT. %	GM/ 4500
10	Deionized Water	99.10556	4459.75	90.66311	4079.84	99.55756	4480.09	95.57511	4300.88
20	Trisodium Phosphate Anhyd. Gran.	0.45200	20.41	4.91200	221.04				
30	KX-6091 (11.3% POAA)	0.44244	19.91	4.42489	199.12	0.44244	19.91	4.42489	199.12
	Total	100.00000	4500.07	100.00000	4500.00	100.00000	4500.00	100.00000	4500.00
	THEORETICAL VALUES	ppm	pH	ppm	pH	ppm	pH	ppm	pH
	POAA	500	6.00	5000	6.00	500	3.00	5000	2.50

INSTRUCTIONS

Add Trisodium Phosphate Anhydrous Granules (item 20) by wt. to weighed amount of DI water and stir with Lab mixer until dissolved. Add (item 30) by wt. to buffered water and final mix 2 min.

RESULTS:

(A) - pH = 6.02
(B) - pH = 5.99
(C) - pH = 2.96
(D) - pH = 2.35

PART II: CORROSION - METALS
14 day Compatibility Test of 15 different materials tested against four different Test Solutions at 50° C. with the test solutions are changed daily.

Test item	Test Solution	Material METALS	Initial Wt. (gms)	Final Wt. (gms)	TWL	CWL	AWL	mpy
1	(A) 500 ppm POAA/Buffered	316 SS	23.5792	23.5791	0.0001	0.0001	0.0000	0.0000
5	(B) 5000 ppm POAA/Buffered	316 SS	23.5194	23.5193	0.0001	0.0001	0.0000	0.0000
9	(C) 500 ppm POAA only	316 SS	23.5764	23.5762	0.0002	0.0001	0.0001	0.0031
13	(D) 5000 ppm POAA only	316 SS	23.5690	23.5689	0.0001	0.0001	0.0000	0.0000
17	CONTROL	316 SS	23.5846	23.5845	0.0001	0.0001		
2	(A) 500 ppm POAA/Buffered	304 SS	17.9651	17.9650	0.0001	0.0000	0.0001	0.0031
6	(B) 5000 ppm POAA/Buffered	304 SS	17.9326	17.9323	0.0003	0.0000	0.0030	0.0938
10	(C) 500 ppm POAA only	304 SS	17.9795	17.9793	0.0002	0.0000	0.0002	0.0063
14	(D) 5000 ppm POAA only	304 SS	17.9993	17.9992	0.0001	0.0000	0.0001	0.0031
18	CONTROL	304 SS	18.1102	18.1102	0.0000	0.0000		
3	(A) 500 ppm POAA/Buffered	7075 Aluminum	12.8716	12.8685	0.0031	0.0002	0.0029	0.2412
7	(B) 5000 ppm POAA/Buffered	7075 Aluminum	12.7575	12.7336	0.0239	0.0002	0.0237	1.9712
11	(C) 500 ppm POAA only	7075 Aluminum	12.8651	12.8392	0.0259	0.0002	0.0257	2.1376
15	(D) 5000 ppm POAA only	7075 Aluminum	12.8718	12.7439	0.1279	0.0002	0.1277	10.6213
19	CONTROL	7075 Aluminum	12.4899	12.4897	0.0002	0.0002		
4	(A) 500 ppm POAA/Buffered	260 Brass	26.4108	26.3763	0.0345	0.0004	0.0341	0.9779
8	(B) 5000 ppm POAA/Buffered	260 Brass	26.4211	26.3307	0.0904	0.0004	0.0900	2.5809
12	(C) 500 ppm POAA only	260 Brass	26.6471	25.6695	0.9776	0.0004	0.9772	28.0233
16	(D) 5000 ppm POAA only	260 Brass	26.4949	18.9759	7.5190	0.0004	7.5186	215.6118
20	CONTROL	260 Brass	26.4352	26.4348	0.0004	0.0004		

PART II: CORROSION - METALS - OBSERVATIONS

Test item	Test Solution	Material METALS	Visual Obervations
1	(A) 500 ppm POAA/Buffered	316 SS	Smooth, shiny silver colored material like control
5	(B) 5000 ppm POAA/Buffered	316 SS	Smooth, shiny silver colored material like control
9	(C) 500 ppm POAA only	316 SS	Smooth, shiny silver colored material like control

-continued

13	(D) 5000 ppm POAA only	316 SS	Smooth, shiny silver colored material like control
17	CONTROL	316 SS	Smooth, shiny silver colored material
2	(A) 500 ppm POAA/Buffered	304 SS	Smooth, shiny silver colored material like control
6	(B) 5000 ppm POAA/Buffered	304 SS	Smooth, shiny silver colored material like control
10	(C) 500 ppm POAA only	304 SS	Smooth, shiny silver colored material like control
14	(D) 5000 ppm POAA only	304 SS	Smooth, shiny silver colored material like control
18	CONTROL	304 SS	Smooth, shiny silver colored material
3	(A) 500 ppm POAA/Buffered	7075 Aluminum	A slt. duller, slt. whiter than control, silver material
7	(B) 5000 ppm POAA/Buffered	7075 Aluminum	A very dull, smokey brown colored material
11	(C) 500 ppm POAA only	7075 Aluminum	A dull, whitish gray colored material
15	(D) 5000 ppm POAA only	7075 Aluminum	A very dull, very whitish gray colored material
19	CONTROL	7075 Aluminum	A slt. dull, silver colored material
4	(A) 500 ppm POAA/Buffered	260 Brass	A mixture of dull gold & pink area colored material
8	(B) 5000 ppm POAA/Buffered	260 Brass	A dull, gold colored material with patches of pink
12	(C) 500 ppm POAA only	260 Brass	A darker dull gold colored material with pink areas
16	(D) 5000 ppm POAA only	260 Brass	A sparkling grainy gold colored material
20	CONTROL	260 Brass	A smooth, shiny, gold colored material

KX-6091 CORROSION STUDY
CALCULATION DATA

4 Metals	DENSITY	AREA in inches squared
316 Stainless Steel	7.98	6.5
304 Stainless Steel;	7.94	6.4
7075 Aluminum	2.81	6.8
260 Brass	8.5	6.52

Time & Temp Tested

14 days at 50° C.
mpy = (534,000 * AWL)/(A * T * D)

(A) = Area (see above)
(T) = Time (336 hrs)
(D) = Density (see above)
AWL = TWL − CWL
TWL = Pre-testing weight − Post-testing weight
CWL = Pre-testing weight of control − Post-testing weight of control
mpy = mils per year

PART III: CORROSION - PLASTICS
Analytical - Observations
KX-6091 CORROSION STUDY
14 day Compatibility Test of 15 different materials tested against four differnt Test Solutions at 50° C. with the test solutions are changed daily.

Test item	Test Solution	Material PLASTICS	Initial Wt. (gms)	Initial Ht. (inches)	Initial Width (Inches)	Initial Thick (inches)	Final Wt. (gms)	% Weight Change	Final Ht. (inches)	% Height Change	Final Width (inches)	% Width Change	Final Thick (inches)	% Thick Chang-es
21	(A) 500 ppm POAA/ Buffered	Polyurethane	3.8348	2.996	0.506	0.128	3.8360	0.0313	2.996	0.0000	0.507	0.1976	0.128	0.0000
27	(B) 5000 ppm POAA/ Buffered	Polyurethane	3.8379	2.996	0.502	0.129	3.8385	0.0156	2.998	0.0668	0.502	0.0000	0.128	−0.7752
33	(C) 500 ppm POAA only	Polyurethane	3.8385	2.999	0.505	0.128	3.8418	0.0860	3.004	0.1567	0.505	−0.1976	0.127	−0.7813
39	(D) 5000 ppm POAA only	Polyurethane	3.8151	2.995	0.504	0.127	3.7411	−1.9397	3.061	2.2037	0.509	0.9921	0.125	−1.5748
45	CON-TROL	Polyurethane	3.8286	2.996	0.505	0.128	3.8200	−0.2248	2.993	−0.1001	0.504	−0.1980	0.128	0.0000
22	(A) 500 ppm POAA/ Buffered	Polyethylene	1.3741	2.991	0.505	0.066	1.3736	−0.0364	2.991	0.0000	0.504	−0.1980	0.066	0.0000

-continued

28	(B) 5000 ppm POAA/ Buffered	Polyethylene	1.3676	2.991	0.505	0.064	1.3675	−0.0073	2.991	0.0000	0.505	0.0000	0.065	1.5625
34	(C) 500 ppm POAA only	Polyethylene	1.3541	2.992	0.504	0.065	1.3541	0.0000	2.991	−0.0334	0.502	−0.3968	0.065	0.0000
40	(D) 5000 ppm POAA only	Polyethylene	1.3586	2.995	0.504	0.066	1.3593	0.0515	2.994	−0.0334	0.502	−0.3968	0.066	0.0000
46	CON-TROL	Polyethylene	1.3668	2.991	0.504	0.068	1.3667	−0.0073	2.989	−0.0669	0.504	0.0000	0.068	0.0000
23	(A) 500 ppm POAA/ Buffered	Polypropylene	1.3792	3.002	0.504	0.066	1.3792	0.0000	3.001	−0.0333	0.503	−0.1984	0.067	1.5152
29	(B) 5000 ppm POAA/ Buffered	Polypropylene	1.3774	2.998	0.503	0.065	1.3775	0.0073	2.999	0.0334	0.503	0.0000	0.066	1.5385
35	(C) 500 ppm POAA only	Polypropylene	1.3793	2.998	0.504	0.065	1.3796	0.0218	2.998	0.0000	0.503	−0.1984	0.065	0.0000

Test item	Test Solution	Material PLASTICS	Initial Wt. (gms)	Initial Ht. (inches)	Initial Width (Inches)	Initial Thick (inches)	Final Wt. (gms)	% Weight Change	Final Ht. (inches)	% Height Change	Final Width (inches)	0.0000	0.065	0.0000
47	CON-TROL	Polypropylene	1.3812	2.997	0.503	0.065	1.3811	−0.0072	2.997	0.0000	0.503	0.0000	0.065	0.0000
24	(A) 500 ppm POAA/ Buffered	Polyvinyl Chloride	2.1801	3.002	0.505	0.066	2.1843	0.1927	3.002	0.0000	0.506	0.1980	0.065	−1.5152
30	(B) 5000 ppm POAA/ Buffered	Polyvinyl Chloride	2.2005	2.997	0.505	0.066	2.2041	0.1636	2.997	0.0000	0.506	0.1980	0.066	0.0000
36	(C) 500 ppm POAA only	Polyvinyl Chloride	2.1734	2.998	0.505	0.065	2.1777	0.1978	2.998	0.0000	0.505	0.0000	0.065	0.0000
42	(D) 5000 ppm POAA only	Polyvinyl Chloride	2.1590	2.998	0.505	0.065	2.1625	0.1621	2.997	−0.0334	0.505	0.0000	0.065	0.0000
48	CON-TROL	Polyvinyl Chloride	2.2048	2.999	0.505	0.056	2.2037	−0.0499	2.998	−0.0333	0.505	0.0000	0.056	0.0000
25	(A) 500 ppm POAA/ Buffered	ABS	1.4724	2.995	0.507	0.061	1.4762	0.2581	2.999	0.1336	0.508	0.1972	0.061	0.0000
31	(B) 5000 ppm POAA/ Buffered	ABS	1.5167	3.003	0.507	0.063	1.5201	0.2242	3.006	0.0999	0.506	−0.1972	0.063	0.0000
37	(C) 500 ppm POAA only	ABS	1.5082	3.000	0.507	0.062	1.5132	0.3315	3.004	0.1333	0.508	0.1972	0.062	0.0000
43	(D) 5000 ppm POAA only	ABS	1.4971	2.995	0.505	0.062	1.5047	0.5076	3.000	0.1669	0.510	0.9901	0.062	0.0000
49	CON-TROL	ABS	1.4822	2.995	0.507	0.062	1.4813	−0.0607	2.995	0.0000	0.508	0.1972	0.062	0.0000
26	(A) 500 ppm POAA/ Buffered	Polyacetal	4.4596	3.003	0.507	0.133	4.5033	0.9799	3.010	0.2331	0.508	0.1972	0.134	0.7519
32	(B) 5000 ppm POAA/ Buffered	Polyacetal	4.3970	3.003	0.507	0.131	4.4302	0.7551	3.009	0.1998	0.507	0.0000	0.132	0.7634

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38	(C) 500 ppm POAA only	Polyacetal	4.4967	3.004	0.506	0.134	4.5441	1.0092	3.014	0.3329	0.508	0.3953	0.135	0.7463
44	(D) 5000 ppm POAA only	Polyacetal	4.3832	3.003	0.507	0.131	4.4264	0.9856	3.012	0.2997	0.508	0.1972	0.132	0.7634
50	CONTROL	Polyacetal	4.4498	3.002	0.506	0.133	4.4454	−0.0989	3.000	−0.0666	0.506	0.0000	0.133	0.0000

Test item	Test Solution	Material PLASTICS	Visual Observations
21	(A) 500 ppm POAA/Buffered	Polyurethane	Dull opaque orange material with semi-transparent boarder
27	(B) 5000 ppm POAA/Buffered	Polyurethane	Dull opaque orange material with semi-transparent boarder and slt. tacky
33	(C) 500 ppm POAA only	Polyurethane	Dull darker opaque orange material with semi-transparent boarder and slt. tacky
39	(D) 5000 ppm POAA only	Polyurethane	Very dark orange, very tacky, completely opaque material that stuck to drying surface resulting in loss of material
45	CONTROL	Polyurethane	A dull, dirty, slt. yellow tinted, semi-transparent material
22	(A) 500 ppm POAA/Buffered	Polyethylene	Slt. whiter material than control
28	(B) 5000 ppm POAA/Buffered	Polyethylene	Slt. whiter material than control
34	(C) 500 ppm POAA only	Polyethylene	Slt. whiter material than control
40	(D) 5000 ppm POAA only	Polyethylene	Slt. whiter material than control
46	CONTROL	Polyethylene	A dull, grayish white material
23	(A) 500 ppm POAA/Buffered	Polypropylene	A white filmy, faintly transparent, more cloudy material than control
29	(B) 5000 ppm POAA/Buffered	Polypropylene	A white filmy, faintly transparent, more cloudy material than control
35	(C) 500 ppm POAA only	Polypropylene	A white heavy filmed, faintly transparent, more cloudy material than control
41	(D) 5000 ppm POAA only	Polypropylene	A white filmy, faintly transparent, more cloudy material than control
47	CONTROL	Polypropylene	A dull gray, semi-transparent material
24	(A) 500 ppm POAA/Buffered	Polyvinyl Chloride	Slt. less shiny and slt. less dark gray material than control
36	(C) 500 ppm POAA only	Polyvinyl Chloride	A dull med. gray material
42	(D) 5000 ppm POAA only	Polyvinyl Chloride	A dull light to medium gray material
48	CONTROL	Polyvinyl Chloride	A dark, shiny gray material
25	(A) 500 ppm POAA/Buffered	ABS	A slt. dull, whiter material than control
31	(B) 5000 ppm POAA/Buffered	ABS	A slt. dull, whiter material than control
37	(C) 500 ppm POAA only	ABS	A slt. dull, much whiter white material than control
43	(D) 5000 ppm POAA only	ABS	A slt. dull bright white material
49	CONTROL	ABS	A slt. dull, vanilla white material
26	(A) 500 ppm POAA/Buffered	Polyacetal	A dull, cleaner white appearance than control
32	(B) 5000 ppm POAA/Buffered	Polyacetal	A dull, cleaner white appearance than control
38	(C) 500 ppm POAA only	Polyacetal	A dull, cleaner white appearance than control
44	(D) 5000 ppm POAA only	Polyacetal	A dull, cleaner white appearance than control
50	CONTROL	Polyacetal	A dull, dirty white material

PART IV: CORROSION - RUBBERS
Analytical - Observations
KX-6091 CORROSION STUDY
14 day Compatibility Test of 15 different materials tested against four different Test Solutions at 50° C. with the test solutions are changed daily.

Test item	Test Solution	Material RUBBERS	Initial Wt. (gms)	Initial Ht. (inches)	Initial Width (inches)	Initial thick (inches)	Final Wt. (gms)	% Weight Change	Final Ht. (inches)	% Height Change	Final Width (inches)	% Width Change	Final Thick (inches)	% Thick Change
51	(A) 500 ppm POAA/ Buffered	Silicon	14.2724	2.930	0.928	0.254	14.2553	−0.1198	2.930	0.0000	0.933	0.5388	0.254	0.0000
56	(B) 5000 ppm POAA/ Buffered	Silicone	15.5707	2.999	1.007	0.249	15.5665	−0.0270	2.995	−0.1334	1.008	0.0993	0.249	0.0000
61	(C) 500 ppm POAA only	Silicone	15.6958	3.013	0.995	0.252	15.7755	0.5078	3.019	0.1991	1.004	0.9045	0.252	0.0000

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66	(D) 5000 ppm POAA only	Silicone	15.1443	2.977	0.994	0.246	15.3760	1.5299	3.003	0.6734	1.005	1.1066	0.249	1.2195
71	CONTROL	Silicone	15.6702	2.970	1.001	0.253	15.6417	−0.1819	2.970	0.0000	1.013	1.1988	0.254	0.3953
52	(A) 500 ppm POAA/ Buffered	Butyl	1.9074	2.999	0.507	0.069	1.9852	4.0789	3.008	0.3001	0.507	0.0000	0.071	2.8986
57	(B) 5000 ppm POAA/ Buffered	Butyl	1.9082	2.999	0.505	0.069	1.9263	0.9485	3.008	0.3001	0.505	0.0000	0.069	0.0000
62	(C) 500 ppm POAA only	Butyl	1.9026	2.996	0.505	0.068	2.0729	8.9509	3.017	0.7009	0.513	1.5842	0.075	10.2941
67	(D) 5000 ppm POAA only	Butyl	1.9097	2.998	0.507	0.069	2.2216	16.3324	3.029	1.0340	0.494	−2.5841	0.078	13.0435
72	CONTROL	Butyl	1.9001	2.998	0.507	0.069	1.8939	−0.3263	2.998	−0.0867	0.504	−0.5917	0.069	0.0000
53	(A) 500 ppm POAA/ Buffered	Vison	23.3725	3.057	1.031	0.248	23.4407	0.2918	3.071	0.4580	1.033	0.1940	0.248	0.0000
58	(B) 5000 ppm POAA/ Buffered	Vison	21.3847	2.984	1.014	0.237	21.4843	0.5598	2.998	0.4692	1.025	1.0848	0.238	0.4219
68	(D) 5000 ppm POAA only	Vison	22.4157	2.964	1.012	0.251	23.7728	6.0542	3.064	3.3738	1.053	4.0514	0.260	3.5857
73	CONTROL	Vison	22.0694	2.988	1.012	0.244	22.0584	−0.0498	2.991	0.1004	1.012	0.0000	0.244	0.0000
54	(A) 500 ppm POAA/ Buffered	EPDM	17.0399	3.042	1.005	0.277	17.1763	0.8005	3.053	0.3616	1.009	0.3980	0.285	2.8881
59	(B) 5000 ppm POAA/ Buffered	EPDM	16.9577	3.033	1.006	0.278	17.2265	1.5851	3.036	0.0989	1.012	0.5964	0.285	2.5180
64	(C) 500 ppm POAA only	EPDM	16.9824	3.059	1.015	0.275	16.9653	−0.1007	3.068	0.2942	1.012	−0.2956	0.282	2.5455
69	(D) 5000 ppm POAA only	EPDM	17.4875	2.985	1.072	0.274	17.9757	2.7917	3.020	1.1725	1.079	0.6530	0.284	3.6496
74	CONTROL	EPDM	16.7254	2.964	1.016	0.278	16.6918	−0.2009	2.959	−0.1687	1.015	−0.0984	0.278	0.0000
55	(A) 500 ppm POAA/ Buffered	BUNA N	15.8678	2.960	1.006	0.242	16.3169	2.8303	2.970	0.3378	1.012	0.5964	0.247	2.0661
80	(B) 5000 ppm POAA/ Buffered	BUNA N	15.9576	2.980	1.020	0.240	16.4275	2.9447	2.989	0.3020	1.019	−0.0980	0.246	2.5000
85	(C) 500 ppm POAA only	BUNA N	16.2737	2.977	1.016	0.246	18.9478	4.1423	2.992	0.5039	1.024	0.7874	0.259	5.2846
70	(D) 5000 ppm POAA only	BUNA N	15.8516	2.956	1.014	0.242	16.5043	4.1176	2.956	0.0000	1.029	1.4793	0.264	9.0909
75	CONTROL	BUNA N	16.0735	2.936	1.107	0.247	16.0328	−0.2532	2.937	0.0341	1.014	−0.2950	0.247	0.0000

Test item	Test Solution	Material RUBBERS	Visual Observations
51	(A) 500 ppm POAA/Buffered	Silicone	A dull, med. - dark orange material similar to control
56	(B) 5000 ppm POAA/Buffered	Silicone	A dull, med. - dark orange material similar to Control
61	(C) 500 ppm POAA only	Silicone	A dull, med. - dark orange material similar to Control
66	(D) 5000 ppm POAA only	Silicone	A dull, med. - dark orange material similar to Control
71	CONTROL	Silicone	A dull, med. - dark orange material
52	(A) 500 ppm POAA/Buffered	Butyl	A dull black material with slt. tacky, slt. rough surface that stuck to drying surface resulting in loss of material
57	(B) 5000 ppm POAA/Buffered	Butyl	A dull black material with very slt. tacky, smooth surface
62	(C) 500 ppm POAA only	Butyl	A black material with tacky, dull, rough surface that stuck to drying surface resulting in loss of material
67	(D) 5000 ppm POAA only	Butyl	A dull black material with very tacky, very rough, surface that stuck to drying surface resulting in loss of material
53	(A) 500 ppm POAA/Buffered	Vison	A dull, charcoal black material with smooth surface

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58	(B) 5000 ppm POAA/Buffered	Vison	A dull, charcoal black material with smooth surface
63	(C) 500 ppm POAA only	Vison	A dull, charcoal black material with slt. rough surface
68	(D) 5000 ppm POAA only	Vison	A dull, charcoal black material with slt. rough surface
73	CONTROL	Vison	A dull, charcoal black material with smooth surface
54	(A) 500 ppm POAA/Buffered	EPDM	A dull, black material with slt. rough surface
59	(B) 5000 ppm POAA/Buffered	EPDM	A dull, black material with slt. blistered surface
64	(C) 500 ppm POAA only	EPDM	A dull, black material with slt. rough surface
69	(D) 5000 ppm POAA only	EPDM	A dull black material with slt. rough surface containing a large blister
74	CONTROL	EPDM	A dull, black material with smooth surface
55	(A) 500 ppm POAA/Buffered	BUNA N	A dull, (darker than control) black material with slt. rough surface
60	(B) 5000 ppm POAA/Buffered	BUNA N	A dark black material with very slt. shiny, fairly smooth surface
65	(C) 500 ppm POAA only	BUNA N	A dark black material with very slt. shiny, slt. blistered surface
70	(D) 5000 ppm POAA only	BUNA N	A dark black material with very slt. shiny, blistered surface
75	CONTROL	BUNA N	A dull, grayish black material with smooth surface

I. Tuberculocidal Efficacy—US Method

The peracetic acid product was tested against *Mycobacterium bovis* (bCG) using the AOAC Confirmatory Test with product concentrations as listed below. The product was diluted in buffer to achieve the pH 6 prior to test. The diluent tested was either tap or distilled water. Test exposure time was 10 minutes. A result of ten no growth tubes per ten tubes tested is required for a passing result Conclusion: successful tuberculocidal results were achieved at product concentrations as low as 1000 ppm POAA.

Product Concentration[a]	Number of no growth tubes/ number of tubes tested[b]
1000 ppm POAA	10/10 - pass
2000 ppm POAA	10/10 - pass
3000 ppm POAA	10/10 - pass
4000 ppm POAA	10/10 - pass

-continued

Product Concentration[a]	Number of no growth tubes/ number of tubes tested[b]
5000 ppm POAA	10/10 - pass

[a] Diluent was tap or distilled water with pH adjusted to 6.

[b] Test results reflect data achieved in three test media, Proskauer-Beck, Kirshners and Middlebrook.

II. Suspension Test—Olympus Method

We have completed the suspension test as requested with the Olympus procedure versus *Bacillus subtilis*. The product was diluted in buffer to achieve the pH 6 prior to test The diluent tested was tap water. Test exposure times are listed below. The data are represented as log reduction of bacterial numbers. Note: the spores were counted after the heat shock treatment, although the test was conducted on a non-heat treated bacterial suspension. Conclusion significant log reductions in microbial numbers were achieved within 10 minutes using 500 ppm POAA. Additional product concentration or exposure time did not increase the efficacy of the product.

Exposure time (minutes)	*Bacillus subtilis* Log Reduction at 20° C. (ppm POAA)				
	250 ppm	500 ppm	1000 ppm	1500 ppm (Henkel-Ecolab test only)	2000 ppm (Ecolab test only)
5 minutes	4.55	6.13	9.48	7.70	9.78
10 minutes	7.98	9.78	9.78	7.68	9.78
20 minutes	9.48	9.78	9.78	7.71	9.78
60 minutes	9.48	9.78	9.78	7.74	9.78
Neutralization control					0.10[A]
Total Inoculum				3.4×10^5 cfu/ml	6.0×10^9 cfu/ml
Spore Inoculum				9.0×10^6 cfu/ml	3.3×10^5 cfu/ml

[A] Neutralizer is 1% sodium thiosulfate and is effective in this test procedure for chemical neutralization of the test substance.

III. Carrier Test—Olympus Method

We have completed the carrier test as requested using the Olympus procedure versus *Bacillus subtilis* and *Mycobacterium terrae*. The product was diluted in buffer to achieve the pH 6 prior to test. The diluent tested was tap water. Test exposure times are listed below. Note: the spores were counted after the heat shock treatment, although the test was conducted on a non-heat treated bacterial suspensions. Conclusion: successful results achieved using 250 ppm POAA within five minutes exposure against both *subtilis* and *Mycobacterium terrae*. Additional product concentration or exposure time did not increase the efficacy of the product.

Exposure time (minutes)	250 ppm			1000 ppm			2500 ppm			5000 ppm		
	CARRIER[A] RESULTS	A[B]	B[C]	CARRIER RESULTS	A	B	CARRIER RESULTS	A	B	CARRIER RESULTS	A	B
	Bacillus subtilis at 20° C. (ppm POAA)											
0 minutes										0/2	2.3×10^4	1.9×10^4
5 minutes	2/2	<1	<1	2/2	<1	<1	2/2	<1	<1	2/2	<1	<1
10 minutes	2/2	<1	<1	2/2	<1	<1	2/2	<1	<1	2/2	<1	<1
20 minutes	2/2	<1	<1	2/2	<1	<1	2/2	<1	<1	2/2	<1	<1
60 minutes	2/2	<1	<1	2/2	<1	<1	2/2	<1	<1	2/2	<1	<1
	Mycobacterium terrae at 20° C. (ppm POAA)											
0 minutes										0/2	3.2×10^4	2.1×10^4
5 minutes	2/2	<1	<1	2/2	<1	<1	2/2	<1	<1	2/2	<1	<1
10 minutes	2/2	<1	<1	2/2	<1	<1	2/2	<1	<1	2/2	<1	<1
20 minutes	2/2	<1	<1	2/2	<1	<1	2/2	<1	<1	2/2	<1	<1
60 minutes	2/2	<1	<1	2/2	<1	<1	2/2	<1	<1	2/2	<1	<1

[A] Number of negative carriers per number of carriers tested.

[B] Plate A is the average cfu/ml of product plus neutralizer mixture.

[C] Plate B is the average cfu/ml of stripper.

D Neutralizer is 1% sodium thiosulfate and is effective in this test procedure for chemical neutralization of the test substance.

IV. Sporicidal Efficacy—US Method

The peracetic add product was tested against *Clostridium sporogenes* using the AOAC Spodcidal Activity of Disinfectants Test with product concentrations as listed below. The product was diluted in buffer to achieve the pH 6 prior to test The diluent tested was tap water. Test exposure time was 3, 4 or 6 hours. A result of twenty no growth tubes per twenty tubes tested is required for a passing result. Conclusion: successful results were achieved at 5000 ppm POAA with an exposure time of 6 hours.

Product Concentration[a]	Exposure Time	Number of no growth tubes/ number of tubes tested[b] Primary Subculture	Secondary Subculture
4000 ppm	3 hours	20/20	0/20
POAA	4 hours	20/20	1/20
	6 hours	19/20	20/20
5000 ppm	3 hours	19/20	6/20

-continued

Product Concentration[a]	Exposure Time	Number of no growth tubes/ number of tubes tested[b] Primary Subculture	Secondary Subculture
POAA	4 hours	20/20	17/20
	6 hours	20/20	20/20
7000 ppm	3 hours	20/20	10/20
POAA	4 hours	20/20	11/20
	6 hours	20/20	20/20

[a] Diluent was tap or distilled water with pH adjusted to 6.

[b] Test results reflect data achieved in three test media, Proskauer-Beck, Kirshners and Middlebrook after heat-shock treatment and reincubation for 72 hours.

Objective:

The objective of this analysis was to evaluate the effect of hydrogen peroxide and acetic acid concentration on the sporicidal efficacy of 150 ppm peracetic acid at 40° C.

Test Method:

Ecolab Microbiological Services SOP CB021-04; *Rate of Kill Antimicrobial Efficacy*. Following exposure to the formula and subsequent neutralization, spores were heat shocked for 13 minutes at 80° C. before plating.

Method Parameters:

Chemical Properties of Each Test Formula

Formula	Theoretical ppm POAA	Theoretical ppm H_2O_2	Theoretical ppm Acetic Acid	pH
A	150	31	159	3.75
B	150	31	309	3.67
C	150	275	159	3.75
D	150	275	309	3.68
E	150	529	159	3.77
F	150	529	309	3.68

Test Substances: Each formula was prepared using a "stock" POAA material (34.1% POAA, 7.13% H_2O_2 and 36.1% acetic acid - Aldrich Chemical) to achieve 150 ppm POAA. H_2O_2 or acetic acid was then added as needed. Please refer to the datasheet attached to this report for preparation information. Since chemical analyses of solutions prepared exactly like those prepared for this study were done previously, and concentrations were found to be accurate, additionalchemical analysis for this study was not perfomed (see MSR #960351, J. Hilgren).
Test System: *Bacillus cereus* spore crop N1009
Test Temperature: 40° C.
Exposure Times: 0.5, 1.0, 1.5, 2.0, 2.5, 3.0 and 3.5 hours
Neutralizer: Fluid Thioglycollate Medium
Plating Media: Dextrose Tryptone Agar
Incubation: 32° C. for 48 hours

Results:

Inoculum Numbers

Organism	Inoculum Test Replicate (CFU/mL) 1	2	3	Average (CFU/mL)
B. cereus Spores	30×10^6	26×10^6	26×10^6	2.7×10^7

Reduction of *B. cereus* Spores at 40° C.

Formula	Exposure Time (hours)	Survivors (CFU/mL)	Log Reduction
A Low Acetic, Low H_2O_2	0.5	$<1.0 \times 10^1$	>6.43
	1.0	$<1.0 \times 10^1$	>6.43
	1.5	$<1.0 \times 10^1$	>6.43
	2.0	$<1.0 \times 10^1$	>6.43
	2.5	$<1.0 \times 10^1$	>6.43
	3.0	$<1.0 \times 10^1$	>6.43
	3.5	$<1.0 \times 10^1$	>6.43
B High Acetic, Low H_2O_2	0.5	$<1.0 \times 10^1$	>6.43
	1.0	$<1.0 \times 10^1$	>6.43
	1.5	$<1.0 \times 10^1$	>6.43
	2.0	$<1.0 \times 10^1$	>6.43
	2.5	$<1.0 \times 10^1$	>6.43
	3.0	$<1.0 \times 10^1$	>6.43
	3.5	$<1.0 \times 10^1$	>6.43
C Low Acetic, Medium H_2O_2	0.5	1.7×10^7	0.20
	1.0	6.0×10^6	0.65
	1.5	2.5×10^6	1.03
	2.0	9.0×10^5	1.48
	2.5	2.1×10^5	2.11
	3.0	6.0×10^4	2.65
	3.5	1.5×10^4	3.26
D High Acetic, Medium H_2O_2	0.5	1.5×10^7	0.26
	1.0	4.9×10^6	0.74
	1.5	2.2×10^6	1.09
	2.0	4.6×10^5	1.77
	2.5	1.2×10^5	2.35
	3.0	3.1×10^4	2.94
	3.5	1.1×10^4	3.39
E Low Acetic, High H_2O_2	0.5	1.5×10^7	0.26
	1.0	5.1×10^6	0.72
	1.5	1.4×10^6	1.29
	2.0	3.1×10^5	1.94
	2.5	3.4×10^4	2.90
	3.0	4.0×10^3	3.83
	3.5	5.6×10^2	4.68
F High Acetic, High H_2O_2	0.5	1.4×10^7	0.29
	1.0	4.7×10^6	0.76
	1.5	1.7×10^6	1.20
	2.0	4.3×10^5	1.80
	2.5	3.3×10^4	2.91
	3.0	5.0×10^3	3.73
	3.5	8.1×10^2	4.52

A graphical representation of the reduction of *B. cereus* spores at 40° C. is presented in FIG. **1**. The lower limit of detection for the test procedure was 10 CFU/mL.

CONCLUSIONS

The sporicidal activity of 150 ppm POAA at 40° C. against *Bacillus cereus* spores was most effective when in the presence of relatively low concentrations of H_2O_2 (≈30 ppm as in Formulas A and B). Reduced *B. cereus* sporicidal efficacy was observed using POAA with the medium and high concentrations of H_2O_2 (≈160 and 300 ppm as in Formulas C through F).

Objective:

The objective of this analysis was to evaluate the effect of hydrogen peroxide and acetic acid concentration on the sporicidal efficacy of 150 ppm peracetic acid at 60° C.

Test Method:

Ecolab Microbiological Services SOP CB021-04; *Rate of Kill Antimicrobial Efficacy*. Following exposure to the formula and subsequent neutralization, spores were heat shocked for 13 minutes at 80° C. before plating.

Method Parameters:

Analytical Chemistry Results - A&P Methods 9403201, 9600300

Formula	Formula Properties (≈ 2 Hours Post Preparation/After 40 min. at 60° C.) ppm POAA	ppm H_2O_2	ppm Acetic Acid	pH
A	147/144	31/33	174/166	3.76/3.67
B	145/144	33/37	346/346	3.71/3.55
C	151/148	277/281	141/143	3.79/3.69
D	151/151	283/280	301/291	3.70/3.60
E	157/154	526/514	136/148	3.81/3.71
F	160/159	533/240*	293/324	3.71/3.62

*No obvious error in analysis was detected, but the result remains in question.

Test Substances: Each formula was prepared using a "stock" POAA material (34.1% POAA, 7.13% H_2O_2 and 36.1% acetic acid - Aldrich Chemical) to achieve 150 ppm POAA. H_2O_2 or acetic acid was then added as needed. Please refer to the datasheet attached to this report for theoretical concentrations and preparation information.
Test System: *Bacillus cereus* spore crop N1009
Test Temperature: 60° C.
Exposure Times: 10, 15, 20, 25, 30 and 40 minutes
Neutralizer: Fluid Thioglycollate Medium
Plating Media: Dextrose Tryptone agar
Incubation: 32° C. for 48 hours

RESULTS:

Inoculum Numbers

	Inoculum Test Replicate (CFU/mL)			Average
Organism	1	2	3	(CFU/mL)
B. cereus Spores	28 × 10^6	22 × 10^6	29 × 10^6	2.6 × 10^7

Reduction of *B. cereus* Spores at 60° C.

Formula	Exposure Time (min.)	Survivors (CFU/mL)	Log Reduction
A Low Acetic, Low H_2O_2	10	<1.0 × 10^1	>6.41
	15	<1.0 × 10^1	>6.41
	20	<1.0 × 10^1	>6.41
	25	<1.0 × 10^1	>6.41
	30	<1.0 × 10^1	>6.41
	40	<1.0 × 10^1	>6.41
B High Acetic, Low H_2O_2	10	<1.0 × 10^1	>6.41
	15	<1.0 × 10^1	>6.41
	20	<1.0 × 10^1	>6.41
	25	<1.0 × 10^1	>6.41
	30	<1.0 × 10^1	>6.41
	40	<1.0 × 10^1	>6.41
C Low Acetic, Medium H_2O_2	10	4.1 × 10^4	2.80
	15	2.0 × 10^2	5.11
	20	<1.0 × 10^1	>6.41
	25	<1.0 × 10^1	>6.41
	30	<1.0 × 10^1	>6.41
	40	<1.0 × 10^1	>6.41
D High Acetic, Medium H_2O_2	10	2.6 × 10^4	3.00
	15	7.0 × 10^1	5.57
	20	<1.0 × 10^1	>6.41
	25	<1.0 × 10^1	>6.41
	30	<1.0 × 10^1	>6.41
	40	<1.0 × 10^1	>6.41
E Low Acetic, High H_2O_2	10	2.4 × 10^4	3.03
	15	2.4 × 10^2	5.03
	20	<1.0 × 10^1	>6.41
	25	<1.0 × 10^1	>6.41
	30	<1.0 × 10^1	>6.41
	40	<1.0 × 10^1	>6.41
F High Acetic, High H_2O_2	10	1.1 × 10^4	3.37
	15	7.0 × 10^1	5.57
	20	<1.0 × 10^1	>6.41
	25	<1.0 × 10^1	>6.41
	30	<1.0 × 10^1	>6.41
	40	<1.0 × 10^1	>6.41

A graphical representation of the reduction of *B. cereus* spores at 60° C. It is shown in FIG. **2**. The lower limit of detection for the test procedure was 10 CFU/mL.

CONCLUSIONS

The sporicidal activity of 150 ppm POAA at 60° C. against *Bacillus cereus* spores was most effective when in the presence of relatively low concentrations of H_2O_2 (≈30 ppm as in Formulas A and B). A decrease in *B. cereus* sporicidal efficacy was observed using the medium and high concentrations of H_2O_2 (≈160 and 300 ppm as in Formulas C through F).

Further testing using Formulas A–F will be conducted at 20° C. to determine the effect of H_2O_2 and acetic acid concentration on sporicidal efficacy of POAA at low temperature.

Objective:

The objective of this analysis was to evaluate the effect of hydrogen peroxides octanoic acid and peroctanoic acid concentration on the sporicidal efficacy of 150 ppm peracetic acid at 40° C.

Test Method:

Ecolab Microbiological Services SOP CB021-04; *Rate of Kill Antimicrobial Efficacy*. Following exposure to the formula and subsequent neutralization, spores were heat shocked for 13 minutes at 80° C. before plating.

Method Parameters:

Chemical Properties of Each Test Formula

Formula	Theoretical ppm POAA	Theoretical ppm H_2O_2	Theoretical ppm AA	Theoretical ppm POOA	Theoretical ppm OA	pH
1	149	36	282	12	39	3.65
2	149	529	282	12	39	3.62
3	149	36	282	50	39	3.64
4	149	529	282	50	39	3.63
5	149	36	282	12	138	3.64
6	149	529	282	12	138	3.63
7	149	36	282	50	138	3.64
8	149	529	282	50	138	3.65

Test Substances: Each formula was prepared using a "stock" POAA material (33.5% POAA, 7.03% H_2O_2 and 37.2% acetic acid - Aldrich Chemical) and a "stock" octanoic/peroctanoic material (11.4% octanoic, 3.4% POOA, 10.29% POAA, 3.70% H_2O_2 - Falcon 15). Hydrogen peroxide, octanoic acid or peroctanoic acid were then added as needed. Please refer to the data sheet attached to this report for preparation information.Prior to this study, chemical analyses of formulas exactly like those used for this study were conducted to determine if ingredient concentrations were close to theoretical and if they were stable over the duration of the efficacy test. Results showed ingredient concentrations to correlate with theoretical and to be stable.

Test System: *Bacillus cereus* spore crop N1009

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Chemical Properties of Each Test Formula

Formula	Theoretical ppm POAA	Theoretical ppm H_2O_2	Theoretical ppm AA	Theoretical ppm POOA	Theoretical ppm OA	pH

Test Temperature: 40° C.
Exposure Times: 5, 10, 15, 20, 25 and 30 minutes
Neutralizer: Fluid Thioglycollate Medium
Plating Medium: Dextrose Tryptone Agar
Incubation: 32° C. for 48 hours

Reduction of B. cereus Spores at 40° C.

Inoculum Numbers

Organism	Inoculum Test Replicate (CFU/mL) 1	2	3	Average (CFU/mL)
B. cereus Spores	56×10^6	42×10^6	35×10^6	4.4×10^7

Reduction of *B. cereus* Spores at 40° C.

Formula	Exposure Time (minutes)	Survivors (CFU/mL)	Log Reduction
1 Low H_2O_2, Low POOA, Low OA	5	3.0×10^1	6.17
	10	$<1.0 \times 10^1$	>6.64
	15	$<1.0 \times 10^1$	>6.64
	20	$<1.0 \times 10^1$	>6.64
	25	$<1.0 \times 10^1$	>6.64
	30	$<1.0 \times 10^1$	>6.64
2 High H_2O_2, Low POOA, Low OA	5	6.4×10^6	0.84
	10	4.3×10^6	1.01
	15	1.8×10^6	1.39
	20	4.0×10^5	2.04
	25	1.2×10^5	2.56
	30	8.1×10^4	2.73
3 Low H_2O_2, High POOA, Low OA	5	$<1.0 \times 10^1$	>6.64
	10	$<1.0 \times 10^1$	>6.64
	15	$<1.0 \times 10^1$	>6.64
	20	$<1.0 \times 10^1$	>6.64
	25	$<1.0 \times 10^1$	>6.64
	30	$<1.0 \times 10^1$	>6.64
4 High H_2O_2, High POOA, Low OA	5	3.4×10^5	2.11
	10	1.6×10^4	3.44
	15	1.9×10^3	4.36
	20	3.0×10^1	6.17
	25	$<1.0 \times 10^1$	>6.64
	30	$<1.0 \times 10^1$	>6.64
5 Low H_2O_2, Low POOA, High OA	5	$<1.0 \times 10^1$	>6.64
	10	$<1.0 \times 10^1$	>6.64
	15	$<1.0 \times 10^1$	>6.64
	20	$<1.0 \times 10^1$	>6.64
	25	$<1.0 \times 10^1$	>6.64
	30	$<1.0 \times 10^1$	>6.64
6 High H_2O_2, Low POOA, High OA	5	4.4×10^6	1.00
	10	4.1×10^5	2.03
	15	7.7×10^4	2.76
	20	5.3×10^4	2.92
	25	1.4×10^4	3.50
	30	5.8×10^3	3.88
7 Low H_2O_2, High POOA, High OA	5	$<1.0 \times 10^1$	>6.64
	10	$<1.0 \times 10^1$	>6.64
	15	$<1.0 \times 10^1$	>6.64
	20	$<1.0 \times 10^1$	>6.64
	25	$<1.0 \times 10^1$	>6.64
	30	$<1.0 \times 10^1$	>6.64
8 High H_2O_2, High POOA, High OA	5	1.2×10^5	2.56
	10	2.0×10^3	4.34
	15	4.0×10^1	6.04
	20	$<1.0 \times 10^1$	>6.64
	25	$<1.0 \times 10^1$	>6.64
	30	$<1.0 \times 10^1$	>6.64

A graphical representation of the reduction of *B. cereus* spores at 40° C. is presented in FIG. **3**. The lower limit of detection for the test procedure was 10 CFU/mL.

CONCLUSIONS

Effect of H_2O_2:

The sporicidal activity of 150 ppm POAA at 400C against *Bacillus cereus* spores was most effective when in the presence of relatively low concentrations of H_2O_2 (≈36 ppm as in Formulas 1, 3, 5 and 7). Reduced *B. cereus* sporicidal efficacy was observed using POAA with the higher concentrations of H_2O_2 (≈529 ppm as in Formulas 2, 4, 6 and 8).

Effects of Octanoic and Peroctanoic Acid:

The sporicidal activity of 150 ppm POAA at 40° C. against *Bacillus cereus* spores increased when the concentrations of octanoic or peroetanoic acid increased. This phenomenon was clearly evident in formulas containing the high concentrations of H_2O_2 (formulas 2, 4, 6 and 8).

On a weight basis, peroctanoic acid had a greater effect on the sporicidal efficacy of 150 ppm POAA against *B. cereus* than octanoic acid. An increase of 38 ppm POOA resulted in a greater log reduction of *B. cereus* spores than an increase of 99 ppm octanoic acid. An additive effect was observed when POOA and octanoic acid were combined.

What is claimed is:

1. A method of sterilizing an endoscope, the method comprising:

(a) providing a buffered sterilizing solution comprising an inorganic buffering agent and at least 100 ppm of a peroxyoctanoic acid at a pH of 5 to 7; and

(b) immersing the endoscope in the sterilizing solution for 5 minutes;

wherein the sterilizing solution contains no effective amount of organic corrosion inhibitor and has a weight ratio of peroxyoctanoic acid to hydrogen peroxide of at least 2:1.

2. The method of claim **1** wherein the sterilizing solution is provided by mixing a first solution and a second solution,

(a) the first solution comprising at least one C_1 to C_{13} carboxylic acid, hydrogen peroxide and water, wherein said first solution contains an octanoic acid, and

(b) the second solution comprising an inorganic buffering agent for pH between about 5 and 7;

wherein the two solutions contain octanoic acid, hydrogen peroxide and the buffering agent at amounts sufficient to provide a mixed solution, which is the sterilizing solution having a buffered pH of 5 to 7, at least 100 ppm of peroxyoctanoic acid, no effective amount of organic corrosion inhibitor, and a weight ratio of peroxyoctanoic acid to hydrogen peroxide of at least 2:1.

3. The method of claim **1** wherein the sterilizing solution also comprises a catalytic amount of a catalyst for peroxidation of a carboxylic acid by the hydrogen peroxide.

4. The method of claim **1** wherein the sterilizing solution has no effective amount of an organic copper or brass corrosion inhibiting compound.

5. The method of claim **1** wherein the inorganic buffering agent comprises a phosphate buffering agent.

6. The method of claim **5** wherein the phosphate buffering agent comprises trisodium phosphate.

* * * * *